

We Claim:

1. A method for the automated isothermal amplification and detection of a specific nucleic acid in a test sample to be tested comprising:
 - 5 a) combining a test sample to be tested with a buffer, a mixture of free nucleotides, specific oligonucleotide primers, and optionally thermostable nucleic acid polymerization enzyme, in a first reaction vessel and placing the reaction vessel in an automated apparatus such that;
 - b) the automated apparatus heats the first reaction vessel to a temperature, and for 10 a time sufficient to denature the nucleic acid in the sample to be tested;
 - c) the automated apparatus cools the first reaction vessel to a temperature such that oligonucleotide primers can specifically anneal to the target nucleic acid;
 - d) the automated apparatus transfers the reaction mixture from the first reaction vessel to a second reaction vessel, and brings the reaction mixture in contact with 15 isothermal nucleic acid amplification enzyme;
 - e) the automated apparatus maintains the temperature of the second reaction vessel at a temperature which allows primer mediated amplification of the nucleic acid;
 - f) the automated apparatus contacts the amplified nucleic acid in the second reaction vessel with a capture nucleic acid specific for the nucleic acid to be tested such 20 that they form a specifically-bound nucleic acid-capture probe complex;
 - g) the automated apparatus optionally washes the specifically captured amplified nucleic acid such that non-specifically bound nucleic acid is washed away from the specifically-bound nucleic acid-capture probe complex;
 - h) the automated apparatus contacts the specifically-bound nucleic acid-capture 25 probe complex with a labeled nucleic acid probe specific for the amplified nucleic acid such that a complex is formed between the specifically amplified nucleic acid and the labeled nucleic acid probe;
 - i) the automated apparatus washes the specifically-bound nucleic acid-capture probe-labeled probe complex such that non-specifically bound labeled probe nucleic acid 30 is washed away from the specifically bound complex;

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j) the automated apparatus contacts the specifically bound complex with a solution wherein an enzymatic reaction between the labeled nucleic acid probe is effected between the solution and the label attached to the nucleic acid such that a detectable signal is generated from the sample in proportion the amount of specifically-bound 5 amplified nucleic acid in the sample;

wherein each of steps h, i and j can be performed sequentially or together;

k) the automated apparatus detects the signal and optionally displays a value for the signal, or optionally records a value for the signal.

10 2. A unified buffer suitable for denaturation of double stranded nucleic acids and annealing of nucleic acids, and is further capable of sustaining the enzymatic activity of nucleic acid polymerization and amplification enzyme.

15 3. A method as in claim 1 wherein the nucleic acid amplification enzyme is placed in the second reaction chamber as a single assay dose amount in a lyophilized pellet, and the reaction chamber is sealed prior to the amplification step.

20 4. An apparatus for the automated detection of more than one nucleic acid target sequences comprising a solid phase receptacle (SPR® pipet-like devise) coated with at least two distinct zones, or a single homogeneous zone of a capture nucleic acid oligonucleotide.

25 5. A method for the automated detection of more than one nucleic acid target sequence comprising contacting a solid phase receptacle (SPR® pipet-like devise) coated with at least two distinct zones, or a single homogeneous zone of a capture nucleic acid oligonucleotide to a sample to be tested and detecting a signal from specifically bound probe.

30 6. A universal internal amplification positive control nucleic acid having the nucleic acid sequence of RIC1.

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7. A universal internal amplification positive control nucleic acid having the nucleic acid sequence of RIC2.

5 8. A method for generating a universal internal amplification positive control nucleic acid consisting of:
generating random nucleic acid sequences of at least 10 nucleotides in length,
screening said random nucleic acid sequence and selecting for specific functionality,
combining in tandem more than one such functionally selected nucleic acid sequences,
10 and screening the combined nucleic acid sequence and optionally selecting against
formation of intra-strand nucleic acid dimers, or the formation of hairpin structures.

9. A method for detecting at least two different target nucleic acid sequences in any one assay reaction comprising:
15 a) coating a solid phase material with at least two capture nucleic acid sequences
which are optionally spatially separated or combined in a single homogeneous mix,
capable of specifically hybridizing to and capturing at least two target nucleic acid
sequences;
b) capturing said target nucleic acid sequences with said capture nucleic acid
20 sequences;
c) detecting said target nucleic acid sequences.